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| 10/509,949 | 10/04/2004 | Gerardo Perez-Camargo | 3714652-00510 | 3101 |
| 29157 | 7590 | 03/01/2010 | | |
| K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690 | | | EXAMINER MAEWALL, SNIGDHA | |
| | | | ART UNIT 1612 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/509,949 | Applicant(s) PEREZ-CAMARGO ET AL. | |
| | Examiner Snigdha Maewall | Art Unit 1612 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29,30,35-39,44 and 53-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-30, 35-39, 44 and 53-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. Receipt of Applicant's arguments/remarks and amended claims all filed on 12/10/09 is acknowledged.

Claims 1-28, 31-34, 40-43, 45-52 and 56 have been cancelled, claims 29, 39 and 54-55, have been amended.

Claims pending in the prosecution are claims **29-30, 35-39, 44 and 53-55**.

(It is to be noted that the instant claims 40-43 have been presented as (previously presented instead of cancelled). Based on the arguments submitted by applicants on 12/10/09, claims 40-43 have been disclosed as being canceled. As such, claims 40-43 are not included in the prosecution. Applicant is requested to file proper claims with correct status.)

New rejections have been made in this Office Action, which are necessitated by claim amendments.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3 Claims 29-30, 35-39, 44 and 53-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 29 and 39, it is not clear if pet animal lacks pancreatic function, or is healthy or condition of pet animal is not clear and thus the claim is indefinite. It is not clear how pancreatic function promoter will increase lipid assimilation and further improve skin and coat condition. Claims as recited do not specify if the lipid assimilation is due to pancreatic function promoter or intestinal function promoter. The claims are thus indefinite. The claims also do not specify any correlation between each and every pancreatic, liver and intestinal function promoter with each and every benefit claimed. It is not clear how buffer, a prebiotic or an intestinal promoter such as carrier will be effective in lipid assimilation. It is also not clear how an alkalanizer or acidifier will increase lipid assimilation. The claims as recited do not link any benefit with any effect individually.

There is no antecedent basis for claims 38 and 53 because claim 29 does not recite any limitation regarding outward appearance, the claims are thus indefinite.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 39, 44 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by USP Howley et al. (USP 4,804,549).

Howley teaches Dog food palatability enhancer, see title. Howley teaches a pet food with better palatability which enhances the acceptability of pet foods. Howley teaches in example 1 lipase, **protease**, whole sweet whey, soy concentrate. Claim 14 teaches soy, whey, egg and protease. **Pancreatic lipase** (a pancreatic function promoter as claimed) is the preferred enzyme, see column 6, lines 11-12. (It is to be noted that soy concentrate comprises omega 3 fatty acid as is evidenced by US Publication 20040121062, paragraph [0012]). The composition which is nutritionally balanced comprising sufficient protein, carbohydrates, fat, vitamins (a liver function promoter as claimed) and minerals is applied to the surface of food product to improve palatability, see column 2, lines 25-30. Since the pet food has nutritionally balanced components, the pet food would increase outward appearance of the pet once administered.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 29-30, 35-39, 44 and 53-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,471,999 ('999) in view of (USP 6,524,619) and further in view of Steiner et al (USP 6,855,506).

'999 teach a pet milk powder as nutritional milk those results in reduced gastrointestinal intolerance (abstract). '999 teaches that the milk powder when administered in an effective amount with the nutritional composition reduces gastrointestinal intolerance and that it may further comprise one or more lipid source, protein source, vitamins and minerals, and teaches a specific aspect which comprises lactose (of micro-organism origin), lactase, **taurine (a liver function promoter)**, arginine and choline (claims 1-9; col. 2, lines 9-lines 26).

'999 teaches that a protein source of whey protein and further supplemented with **taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40)**. (Lactic acid reads on pancreatic function promoter, therefore, it is obvious that an acidifier such as lactic acid produced by probiotics help in improving intestinal balance, it is to be noted that probiotics are known to produce lactic acid and acetic acid, a pH modifying agent, which inhibit growth of bacteria, see instant specification page 8, paragraph 30).

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'999 teaches chicory fibers, inulin, fructooligosaccharides with the probiotic micro-organism have a symbiotic relationship for promoting beneficial effects (col. 4, lines 9-14).

'999 teaches that the amount of nutritional composition is to be fed to a mammal each day depends on factors such as age, type of mammal (dogs and cats), and other nutritional sources (col. 4, lines 25-36). Examples 1 and 2 teach mixing the milk powder, galactosidase (lactase amino), **vitamins**, minerals, and soybean oil, and adding water to provide nutritional supplement to **dogs and puppies or cats**. '999 teaches that a protein source of whey protein and further supplemented with taurine and a **probiotic micro-organism** which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40). '999 teach omega fatty acids such as **soybean oil** (It is to be noted that fish oil is known in the art to comprise omega fatty acids such as EPA and DHA ,see USP 6,608,223) and in Examples 1-2 (col. 3, lines 15-20). Soybean oil and vitamin has been shown to be at 1.7 percent by weight and 0.4% by weight respectively in Example 1 in column 4. The amount of soybean oil (which comprises omega fatty acid reads on a fatty acid with profile as claimed in instant claim 45) is within the claimed range of from about 0.1% to 20%. Examples 1 and 2 teach mixing the milk powder, galactosidase (lactase amino, an enzyme), vitamins, minerals, and soybean oil, and adding water to provide nutritional supplement to **dogs and puppies or cats**.

'999 teaches that a protein source of **whey protein** and further supplemented with **taurine** and a probiotic micro-organism which beneficially effects the host by

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improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40) (according to the limitations of claims 55 and 58-60).

The reference does not teach correlation of taurine with lipid assimilation.

'619 teaches taurine enhances absorption of drug especially lipid soluble drugs and also teaches that bile salts are synthesized in the liver from cholesterol conjugated with taurine and within the gastrointestinal lumen these bile salts play an essential role in lipid absorption and fat transport, see column 22 and 23, lines 63-68 and 15-25.

A skilled artisan would thus have been motivated to provide a pet with an edible composition comprising liver function promoter such as taurine as taught by '999 in order to help in lipid absorption motivated by the teachings of '619. It would have been obvious to one of ordinary skill in the art to optimize the amount of liver function promoter such as taurine to obtain best possible results by doing experimental manipulations because '999 teaches soybean oil (reads on both liver function promoter and intestinal function promoter as taught in instant specification) and vitamins in 1.7% and 0.4% amount (claimed as liver function promoter in instant specification), as such it would have been within the purview of a skilled artisan to optimize the amount of the claimed liver function promoter, taurine to obtain best possible results and come to the claimed invention.

The references discussed above, '999 and '619 do not teach pancreatic lipase and its association with lipid assimilation.

Steiner et al. teach utilization of pancreatic lipase as an enzyme essential for the absorption of dietary long chain triglycerides fatty acids. (See column 2, lines, 1-2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize pancreatic extract lipase in the teachings of '999. One of ordinary skill in the art would have been motivated to do so because secondary reference teaches that pancreatic lipase is essential for the absorption of dietary triglycerides fatty acids. Since '999 is directed to nutritional product which reduces gastrointestinal intolerances, one would have been motivated to add pancreatic extract lipase in order help in absorption of long chain fatty acids during digestion process as taught by secondary references.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. Claims 29-30, 35-39, 44 and 53-54 are rejected 35 U.S.C. 103(a) as being unpatentable over US Patent No. Fuchs et al (WO 02/15719 ('719) in view of (USP 6,524,619) and further in view of Steiner et al (USP 6,855,506).

'719 discloses a method of treatment which comprises administering an effective amount of the composition which contains whey protein to improve, promote, maintain intestinal function and mucins a patient or **companion animal** (abstract, claims 1-2 and 14-20, pg. 6 lines 5-10; pg. 12 lines 3-21).

Example 4 teaches a nutritional supplement comprising whey protein and **probiotic bacteria**. (It is to be noted that probiotics are known to produce **lactic acid** and acetic acid, a pH modifying agent, which inhibit growth of bacteria, see instant specification page 8, paragraph 30).

'719 teaches that the nature of whey protein and the fact that it is capable of being easily digested, the composition has a beneficial effect in patients with limited appetite due illness, surgery, chronic gastritis, etc (pg. 4, line 31-pg. 5, line 6), and that the addition of a probiotic micro-organism (pancreatic function promoter as claimed) provides the advantage of restoring the natural balance of the intestinal flora following antibiotic therapy (pg. 6, lines 7-10). Whey protein is taught by applicant to be a fat transportation aid agent and carrier (instant spec pg. 10, 13-20). The amount of Whey protein is taught to be 4.8% and vitamins and minerals to at least 5% of RDA in example 1 on page 13, '719 also teaches including a probiotic (claim 13, pg. 5, and lines 27-30). '719 teach including **taurine and** (claim 12, pg. 5, lines 18-25; pg. 6, lines 27-29), (claimed as liver function promoter in instant claims). '719 teach a lipid source including **omega-3 fatty acids** (abstract, claim 1). (Claimed as intestinal function promoter in instant claims).

'719 teach a nutritional supplement comprising whey protein and omega-3 fatty acids (abstract, claims 1-2). The reference teaches various amounts of polyunsaturated fatty acids including omega 3 fatty acid to be 15 to 30%, see page 8, lines 10-20. The reference teaches vitamins (claimed as liver function promoter in instant application), see page 9, and lines 1-14.

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The references disclosed above do not teach correlation of taurine with lipid assimilation.

'619 teaches taurine enhances absorption of drug especially lipid soluble drugs and also teaches that bile salts are synthesized in the liver from cholesterol conjugated with taurine and within the gastrointestinal lumen these bile salts play an essential role in lipid absorption and fat transport, see column 22 and 23, lines 63-68 and 15-25.

A skilled artisan would thus have been motivated to provide a pet with an edible composition comprising liver function promoter such as taurine as taught by '719 in order to help in lipid absorption motivated by the teachings of '619. It would have been obvious to one of ordinary skill in the art to optimize the amount of liver function promoter such as taurine to obtain best possible results by doing experimental manipulations because '719 teaches soybean oil (reads on both liver function promoter and intestinal function promoter as taught in instant specification) and vitamins in 1.7% and 0.4% amount (claimed as liver function promoter in instant specification), as such it would have been within the purview of a skilled artisan to optimize the amount of the claimed liver function promoter, taurine to obtain best possible results and come to the claimed invention.

The references discussed above, '719 and '619 do not teach pancreatic lipase and its association with lipid assimilation.

Steiner et al. teach utilization of pancreatic lipase as an enzyme essential for the absorption of dietary long chain triglycerides fatty acids. (See column 2, lines, 1-2).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize pancreatic extract lipase in the teachings of '999. One of ordinary skill in the art would have been motivated to do so because secondary reference teaches that pancreatic lipase is essential for the absorption of dietary triglycerides fatty acids. Since '999 is directed to nutritional product which reduces gastrointestinal intolerances, one would have been motivated to add pancreatic extract lipase in order help in absorption of long chain fatty acids during digestion process as taught by secondary references.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over USP 6,471,999 ('999) in view of in view of Steiner et al (USP 6,855,506) and further in view of USP 6,228,367 and USP (6,610,007).

The teachings of '999 do not teach correlation of omega 3 fatty acid with lipid assimilation.

'367 claims in claim 1 a food supplement formulation of fish oil and lipase (the instant specification defines a pancreatic extract to be a lipase pg. 12, lines 1-3) (abstract, claim 1). The supplement of '367 improves bodily functions including fat

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metabolism, etc (col. 2, lines 26-30). The fish oil has specific fatty acid profile. It would have been obvious to one of ordinary to substitute fish oil in the teachings of the references discussed above because '999 teaches inclusion of omega 3-fatty acids in the composition and fish oil is known in the art to comprise omega fatty acids as is evident by USP 6,608,223.

The teachings of combined references taught above do not disclose correlation of fish oil (intestinal mucosa function promoter) with lipid assimilation .

'0007 teaches fish oil enhances absorption of vitamin E tocopherol and vitamin A, retinol and teaches lipid digestion and absorption in rat model, see example 2 in column 11 and 12, lines 60-68 and 1-5 respectively. It is therefore evident that inclusion of fish oil which contains omega 3 fatty acids would help in lipid digestion and absorption and thus it is the position of the examiner that a nutrition regimen comprising pancreatic lipase as taught by '999 and omega 3 fatty acid an intestinal function promoter would help in lipid assimilation based on the teachings of the prior art discussed herein.

Response to Arguments

10. Applicant's arguments with respect to claims 29-30, 35-39, 44 and 53-55 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612